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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/928,639 | 08/13/2001 | Mikhail Sergeevich Shchepinov | GJE-53X | 8021 |

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EXAMINER

GAKH, YELENA G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1743

DATE MAILED: 07/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,639

Applicant(s)

SHCHEPINOV, MIKHAIL
SERGEEVICH

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 32, 33 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. A Response to Election/Restriction, filed on 06/18/03, is acknowledged. Claims 1-37 are pending in the Application. Claims 18-31 and 34-36 are withdrawn from consideration. Claims 1-17, 32-33 and 37 are considered on merits.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Method for calibrating mass spectrometers with trityl mass-tags".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17, 32-33 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not recite any relation between compound Y and compounds R-X, and therefore it is not clear, how they are connected and why measuring MS of R-X can provide molecular mass of Y.

Claim 17 provides for the use of a compound of Formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

Art Unit: 1743

results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In claim 32 it is not clear, if measuring the molecular mass of a compound Y requires comparing m/e of the compounds Y and R-X.

Method of claim 37 is not clear. What is its purpose? Studying mass spectra of different trityl groups?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-6 and 12-13 and 16** are rejected under 35 U.S.C. 102(b) as being anticipated by Shchepinov et al. (Innovation and Perspectives in Solid Phase Synthesis, Int. Symposium, 1999).

Shchepinov et al. disclose the following: “a new method of encoding has been developed based on the high desorption rate of triphenylmethyl-based tags under the conditions of LDI-TOF-MS, which is simpler than chromatog.-based methods. The trityl cations can be detected by LDI-TOF anal. with or without matrix. Combinatorial libraries of oligonucleotides on TentaGel were synthesized by a split- and mix-strategy using 5'-DMT or 5'-Fmoc nucleoside phosphoramidites. Trityls with different masses were utilized to tag the bases coupled at each step in the synthesis, by coupling different amines to activated carboxyl groups on the trityl moiety. Hybridization from the library selected the beads with specific oligonucleotide. The tags, which desorb and fly extremely well in the pos. mode of a LDI process, may be cleaved by either an acid or directly by laser during (MA) LDI-TOF. These tags are capable for encoding in strategies not involving strong acids, such as oligonucleotide and peptide synthesis and small mol. combinatorial libraries” (Abstract). MS measurements of combinatorial libraries

Art Unit: 1743

comprising trityl tags provide the steps of indicated claims, since compounds of unknown molecular mass and R-X are subjected to MS analysis.

7. **Claim 37** is rejected under 35 U.S.C. 102(b) as being anticipated by Berlin et al. (Org. Mass Spectr.).

Berlin discloses mass spectrometry of five classes of trityl compounds, including 25 trityl derivatives.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 7-11** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shchepinov.

While no full text of Shchepinov's paper is available to the examiner at this time, and no particular trityl compounds are disclosed in the Abstract, it is easy to assume that they are the same compounds as those disclosed in WO 99/60007 by the same authors, i.e. trityl compounds, R¹, R² and R³ groups of which "carry a substituent selected from C₁-C₂₀ alkoxy or hydrocarbyl either unsubstituted or substituted by carboxylic acid, sulphonic acid, nitro, cyano, hydroxyl,

Art Unit: 1743

thiol, primary, secondary or tertiary amino, primary or secondary amide, anhydride, carbonyl halide or active ester" (page 8, lines 28-31 and page 9, line 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh
July 14, 2003

